labeling, in-process materials, and finished products that have been released for use in infant formula production and shall permit the easy reading of instruments and controls necessary in processing, packaging, and laboratory analysis. Any lighting fixtures directly over or adjacent to exposed raw materials, in-process materials, or bulk (unpackaged) finished product shall be protected to prevent glass from contaminating the product in the event of breakage.

(d) A manufacturer shall provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate the infant formula; and shall minimize the potential for contamination of raw materials, in-process materials, final product infant formula, packing materials, and infant formula-contact surfaces, through the use of appropriate measures, which may include the use of air filtration.

(e) All rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents shall be stored and used in a manner that protects against contamination of infant formula.

(f) Potable water used in the manufacture of infant formula shall meet the standards prescribed in the Environmental Protection Agency's (EPA's) Primary Drinking Water regulations in 40 CFR part 141, except that the water used in infant formula manufacturing shall not be fluoridated or shall be defluoridated to a level as low as possible prior to use.

(1) The water shall be supplied under continuous positive pressure in a plumbing system that is free of defects that could contaminate an infant formula.

(2) A manufacturer shall test representative samples of the potable water drawn at a point in the system at which the water is in the same condition that it will be when it is used in infant formula manufacturing.

(3) A manufacturer shall conduct the tests required by paragraph (f)(2) of this section with sufficient frequency to ensure that the water meets the EPA's Primary Drinking Water Regulations but shall not conduct these tests less frequently than annually for chemical contaminants, every 4 years for radiological contaminants, and weekly for bacteriological contaminants.

(4) A manufacturer shall make and retain records, in accordance with §106.100(f)(1), of the frequency and results of testing of the water used in the production of infant formula.

(g) There shall be no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for infant formula manufacturing.

(h) Only culinary steam shall be used at all direct infant formula product contact points. Culinary steam shall be in compliance with the 3–A Sanitary Standards, No. 60903, which is incorporated by reference at §106.160. Boiler water additives in the steam shall be used in accordance with §173.310 of this chapter.

(i) Each infant formula manufacturing site shall provide its employees with readily accessible toilet facilities and hand washing facilities that include hot and cold water, soap or detergent, single-service towels or air dryers in toilet facilities. These facilities shall be maintained in good repair and in a sanitary condition at all times. These facilities shall provide for proper disposal of the sewage. Doors to the toilet facility shall not open into areas where infant formula, ingredients, containers, or closures are processed, handled, or stored, except where alternate means have been taken to protect against contamination.

[79 FR 8059, Feb. 10, 2014, as amended at 79 FR 33070, June 10, 2014]

§ 106.30 Controls to prevent adulteration caused by equipment or utensils.

(a) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are of appropriate design and are installed to facilitate their intended function and their cleaning and maintenance.

(b) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or

holding of an infant formula are constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. A manufacturer shall ensure that such equipment and utensils are designed to be easily cleanable and to withstand the environment of their intended use and that all surfaces that contact ingredients, in-process materials, or infant formula are cleaned and sanitized, as necessary, and are maintained to protect infant formula from being contaminated by any source. All sanitizing agents used on such equipment and utensils that are regulated as pesticide chemicals under 21 U.S.C. 346a(a) shall comply with the Environmental Protection Agency's regulations established under such section, and all other such sanitizers shall comply with all applicable Food and Drug Administration laws and regulations.

(c) A manufacturer shall ensure that any substance, such as a lubricant or a coolant, that is required for operation of infant formula manufacturing equipment and which would render the infant formula adulterated if such substance were to come in contact with the formula, does not come in contact with formula ingredients, containers, closures, in-process materials, or with infant formula product during the manufacture of an infant formula.

(d) A manufacturer shall ensure that each instrument used for measuring, regulating, or controlling mixing time and speed, temperature, pressure, moisture, water activity, or other parameter at any point, step, or stage where control is necessary to prevent adulteration of an infant formula during processing is accurate, easily read, properly maintained, and present in sufficient number for its intended use.

(1) The instruments and controls shall be calibrated against a known reference standard at the time of or before first use and thereafter at routine intervals, as specified in writing by the manufacturer of the instrument or control, or as otherwise deemed necessary to ensure the accuracy of the instrument or control. The known reference standard shall be certified for accuracy at the intervals specified in writing by the manufacturer of the instrument or control, or at routine intervals otherwise deemed necessary to ensure the accuracy of the instrument or control. A manufacturer shall make and retain records of the calibration activities in accordance with § 106.100(f)(2).

(2) Instruments and controls that cannot be adjusted to agree with the reference standard shall be repaired or replaced.

(3) If calibration of an instrument shows a failure to meet a specification for a point where control is deemed necessary to prevent adulteration of infant formula product, a written evaluation of all affected product, and of any actions that need to be taken with respect to that product, shall be made, in accordance with § 106.100(f)(2).

(e) The following provisions apply to thermal processing and cold storage of infant formulas:

(1) Equipment and procedures for thermal processing of infant formula packaged in hermetically sealed containers shall conform to the requirements in 21 CFR parts 108 and 113.

(2)(i) Except as provided in paragraph (e)(2)(ii) of this section, a manufacturer shall maintain all areas of cold storage at a temperature of 40 °F (4.4 °C) or below.

(ii) A manufacturer may maintain a cold storage area for an in-process infant formula or for a final infant formula at a temperature not to exceed 45 °F (7.2 °C) for a defined period of time provided that the manufacturer has scientific data and other information to demonstrate that the time and temperature conditions of such storage are sufficient to ensure that there is no significant growth of microorganisms of public health significance during the period of storage of the in-process or final infant formula product.

(3)(i) Cold storage compartments and thermal processing equipment shall be equipped with easily readable, accurate temperature-indicating devices.

(ii) A manufacturer shall ensure that the temperature of each cold storage compartment is maintained by:

(A) Monitoring the temperature of the cold storage compartment on a temperature-indicating device and recording this temperature in a record with such frequency as is necessary to

ensure that temperature control is maintained;

(B) Equipping the cold storage compartment with one or more temperature-recording devices that will reflect, on a continuing basis, the true temperature, within the compartment;

(C) Equipping the cold storage compartment with a high temperature alarm that has been validated to function properly and recording the temperature in a record with such frequency as is necessary to ensure that temperature control is maintained; or

(D) Equipping the cold storage compartment with a maximum-indicating thermometer that has been validated to function properly and recording this temperature in a record with such frequency as is necessary to ensure that temperature control is maintained.

(iii) A manufacturer shall, in accordance with §106.100(f)(3), make and retain records of the temperatures recorded in compliance with §106.30(e)(3)(ii).

(4) When a manufacturer uses a temperature-recording device for a cold storage compartment, such device shall not read lower than the reference temperature-indicating device.

(5) A manufacturer shall monitor the temperature in thermal processing equipment at points where temperature control is necessary to prevent adulteration. Such monitoring shall be at such frequency as is required by regulation or is necessary to ensure that temperature control is maintained.

(f) A manufacturer shall ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula.

(1) An individual qualified by education, training, or experience to conduct such a review shall review all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed.

(2) A manufacturer shall make and retain records on equipment cleaning, sanitizing, and maintenance, in accordance with §106.100(f)(4).

(g) A manufacturer shall ensure that compressed air or other gases that are mechanically introduced into infant formula, that are used to clean any equipment, or that come into contact with any other surface that contacts ingredients, in-process materials, or infant formula product are treated in such a way that their use will not contaminate the infant formula with unlawful or other chemical, physical, or microbiological contaminants. When compressed gases are used at product filling machines to replace air removed from the headspace of containers, a manufacturer shall install, as close as practical to the end of the gas line that feeds gas into the space, a filter capable of retaining particles 0.5 micrometer or smaller.

[79 FR 8059, Feb. 10, 2014, as amended at 79 FR 33071, June 10, 2014]

§ 106.35 Controls to prevent adulteration due to automatic (mechanical or electronic) equipment.

(a) For the purposes of this section:

(1) ''Hardware'' means all automatic equipment, including mechanical and electronic equipment (such as computers), that is used in production or quality control of infant formula.

(2) ''Software'' means any programs, procedures, rules, and associated documentation used in the operation of a system.

(3) ''System'' means a collection of components (including software and hardware) organized to accomplish a specific function or set of functions in a specified environment.

(4) ''Validation'' means establishing documented evidence that provides a high degree of assurance that a system will consistently produce a product meeting its predetermined specifications and quality characteristics. Validation can be accomplished through any suitable means, such as verification studies or modeling.

(b) All systems shall be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of this part.

(1) A manufacturer shall ensure, at any point, step, or stage where control is necessary to prevent adulteration of the infant formula, that all hardware is routinely inspected and checked according to written procedures and that